UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,296	09/29/2003	Ronan Thornton	P1818 US (2650/106)	4107

7590 03/15/2006

Medtronic Vascular, Inc.
3576 Unocal Place
Santa Rosa, CA 95403

EXAMINER	
PRONE, CHRISTOPHER D	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,296	THORNTON ET AL.	
	Examiner	Art Unit	
	Christopher D. Prone	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/05 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-25 and 28-38 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5,380,299 Fearnot.

In regards to claims 17 and 25, Fearnot discloses the same invention being a catheter described in column 1 on lines 11-21 and a drug-polymer coated stent, comprising: a stent framework referenced as element 12, a laminated drug-polymer coating disposed on the stent framework, the laminated drug-polymer coating including a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include a

first therapeutic agent and a first polymer, which is inherently cured by one of thermal activation, electrical activation, or ionizing irradiation (figure 5) (2:10-25 of Fearnot).

In regards to claims 18, 19, 28, and 29, Fearnot discloses the same invention wherein the stent framework comprises a metallic base made of nitinol described in column 3 on lines 7-22.

In regards to claims 20, 24, 30, and 34, Fearnot discloses the same invention wherein the first and second therapeutic agents are selected from the group consisting of rapamycin, a rapamycin derivative, a rapamycin analogue, camptothecin, dexamethasone, 5-fluorouracil, a bioactive agent, a pharmaceutical drug, a therapeutic substance, and a combination thereof described in column 1 on lines 60-68 of Fearnot.

In regards to claims 21 and 31, Fearnot discloses the same invention wherein a concentration of the first therapeutic agent is modulated to provide a predetermined drug-release profile described in column 2 on lines 18-22 of Fearnot.

In regards to claims 22, 23, 32, and 33, Fearnot discloses the same invention comprising: at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the thin barrier layer includes a cured second polymer and a second therapeutic agent shown in figure 5 and described in column 2 on lines 10-25 of Fearnot.

In regards to claim 35 Fearnot discloses the same invention comprising a drug-polymer coated stent including a laminated drug-polymer coating having a plurality of thin drug-polymer layers, wherein the thin drug-polymer layers include at least one therapeutic agent and a cured first polymer described in column 2 in lines 10-25;

wherein it is inherent that the invention of Fearnot comprises inserting a drug-polymer coated stent within a vessel of a body and eluting at least one therapeutic agent from the laminated drug-polymer coating into the body

In regards to claim 36, Fearnot discloses the same invention wherein the drug-polymer coated stent includes at least one thin barrier layer positioned between one or more thin drug-polymer layers, wherein the thin barrier layer includes a cured second polymer shown in figure 5 and described in column 2 on lines 10-25 of Fearnot.

In regards to claim 37, Fearnot discloses the same invention wherein the thin barrier layers control an elution rate of at least one therapeutic agent described in column 2 on lines 18-22 of Fearnot.

In regards to claim 38, Fearnot discloses the same invention comprising selecting the cured first polymer and the cured second polymer based on a predetermined elution rate of at least one therapeutic agent described in column 2 on lines 18-22 of Fearnot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. 103 as being unpatentable over United States Patent 5,380,299 Fearnot in view of United States Patent 6,251,136 Guruwaiya.

Fearnot discloses the invention substantially as claimed being a catheter and drug-polymer coated stent. However, Fearnot does not disclose use of an inflation balloon and a sheath.

Guruwaiya teaches the use of a balloon catheter with a sheath in the same field of endeavor for the purpose of securing the stent to the catheter during delivery and securing the stent to the operating site after delivery.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the sheath and balloon catheter of Guruwaiya with drug-polymer coated stent of Fearnot in order to provide a more secure delivery device for the stent.

Response to Arguments

Applicant's arguments filed 11/28/05 have been fully considered but they are not persuasive. The applicant argues that Fearnot does not disclose that the first polymer is cured with one of thermal activation, electrical activation, or ionizing irradiation. However this claim language is considered to be a recitation of product by process, and as so the claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

> "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted) (Claim was directed to novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., In re Garnero, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations).

Applicant is advised to see MPEP section 2113 for more details. Therefore since Fearnot discloses all the claimed structural requirements it is fully capable of being prepared in the manner recited by the newly amended claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher D Prone
Examiner
Art Unit 3738

CDP

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700